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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,900	09/18/2003	William F. McKay	4002-3376/PC445.00	8517

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MEDTRONIC
Attn: Noreen Johnson - IP Legal Department
2600 Sofamor Danek Drive
MEMPHIS, TN 38132

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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07/02/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/666,900

Applicant(s)

MCKAY ET AL.

Examiner

Brian E. Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-19,27,45-47 and 49-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-19,27,45-47 and 49-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/13/09 has been entered.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the limitation that the folded configuration has a multiplicity of "pleated" folds was not found in the written description.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-19,27,45-47,49,50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pulling a drawstring to cause folding

of tissue, does not reasonably provide enablement for the ability to restrain the tissue to cause the folding. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicant in the remarks of 4/13/09 state the surgeon may “restrain or hold” the tissue to cause folding while pulling on a drawstring. However, the written description fails to explain how such a step is accomplished or the possible other means of restraining or holding the tissue in place, such as with anchoring means.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 51-53,56-58 are rejected under 35 U.S.C. 102(a) as being anticipated by Gabbay (WO 02/39889). Fig. 4 shows an intervertebral disc device having a length of natural tissue **48** with a “drawstring” **50** attached at or near its first end and passes through the tissue at a plurality of sites of at least three. Because the tissue is folded, the string extends through the tissue to or near the second end to keep together the folds and draw together the ends and can be said that it extends beyond the second end such that it can be secured or knotted such that the string does not become removed from the tissue. It has been held that the recitation that an element is “adapted to” perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69

USPQ 138. The string is "adapted to be" pulled. Regarding claim 52, Gabbay discloses natural tissue, page 9, lines 8-13. With respect to claim 53, Gabbay discloses pericardium tissue, page 8, lines 17,18. Regarding claims 57,58, it can be seen that the string passes through at least ten sites on the tissue.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 54,55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gabbay (WO 02/39889) in view of Sybert et al. (2002/107570). Gabbay is explained above. However, Gabbay fails to disclose the natural tissue is SIS or braided construction. Sybert et al. teach that natural tissue (small intestine submucosa) can be used to form a prosthetic device, paragraph 31. Sybert additionally teaches that braided construction can be used in tissue implants for providing greater strength, paragraphs 67-70,72. It would have been obvious to one of ordinary skill in the art to utilize SIS as taught by Sybert et al. for the natural tissue in Gabbay's spinal implant because of the abundance of SIS and its durability. Additionally it would have been obvious to one of ordinary skill in the art to use braided constructions as taught by Sybert et al. for the implant of Gabbay such that it increases the strength of the prosthesis to better stabilize the spine.

Claims 17,18,27,45-47,49,50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muhanna (6936070) in view of Lambrecht et al. (2002/151979).

Muhanna discloses (Fig. 4B) an implant **16** having a length introduced into the disc **21** space. It can be seen that the implanted or second folded configuration has a multiplicity of folds. The Examiner is not giving any special definition to the term "pleated" as it means: a fold of definite, even width made by doubling a material or the like upon itself and pressing or stitching it in place according to dictionary.com. Thus, it can be deduced that the tissue folded over of Muhanna has a pleated configuration.

Muhanna also discloses natural tissue, such as pericardium can be used for the material, col. 4, lines 38,50-54. Fig. 3A illustrates the tissue can include a drawstring **15**. However, Muhanna fails to disclose the drawstring passes through the tissue at a multiplicity of sites along the length of the tissue. Lambrecht et al. teach (Fig. 49G) that the drawstring **406** passes through the implant or tissue at a multiplicity of sites.

Lambrecht also teaches the filament aids in manipulating the implant or tissue in the site of implantation, paragraph 213. As best understood, it would have been obvious to one of ordinary skill in the art to use a multiplicity of sites to secure the drawstring as taught by Lambrecht et al. with the tissue implant inserted in the disc by the method of Muhanna such that it is properly spaced in the disc space entirely to fill the area. Since the site accessed in the patient is minimal or small, the Examiner considers the tissue site or vertebral disc and annulus to aid in holding the tissue essentially in place as the implant is inserted and once it begins to fill the area it causes folding. With respect to claims 45,46, Lambrecht discloses (paragraph 207) the drawstring passes through a multiplicity of sites of the implant of at least 5, see Figs. 49G,50F. Regarding claim 47, Lambrecht fails to explicitly disclose at least ten sites of passing the drawstring through

the implant. It would have been an obvious expedient to one of ordinary skill in the art to pass the drawstring through at least 10 sites on the implant since such a modification only involves routine skill in the art and provides predictable results in strengthening the tissue and the ability to manipulate it. Regarding claim 49, Muhanna fails to disclose the tissue is braided. Lambrecht et al. teach (paragraph 209) that the tissue material can be woven (braided). It would have been obvious to one of ordinary skill in the art to use a braided tissue as taught by Lambrecht with the method of Muhanna such that it reinforces or gives a stronger implant material. With respect to claim 50, Muhanna fails to disclose a cannula to deliver the tissue to the disc space. Lambrecht et al. teach the use of a cannula to deliver a tissue implant to the disc space, paragraphs 208,210,211. It would have been obvious to one of ordinary skill in the art to use a cannula as taught by Lambrecht et al. with the method of Muhanna to deliver the implant in the disc space and not have it possibly be placed outside the area inadvertently.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Muhanna '070 in view of Lambrecht et al. (2002/151979) as applied to claim 27 above, and further in view of Sybert et al. (2002/107570). Muhanna as modified by Lambrecht et al. is explained supra. However, Muhanna in view of Lambrecht fail to teach small intestine submucosa for the tissue implant. Sybert et al. is also explained above. It would have been obvious to one of ordinary skill in the art to use SIS as taught by Sybert et al. with the method of repairing a disc disclosed by Muhanna modified in view of Lambrecht et al. such that it gives the ability to use a versatile tissue that can be easily obtained.

Response to Arguments

Applicant failed to submit an argument under the heading "Remarks" pointing out disagreements with the examiner's contentions with respect to the specification objection. Since no such comments were made, the Examiner has given the term "pleated" the broadest definition since the term was not found in the specification.

Applicant's arguments filed 4/13/09 have been fully considered but they are not persuasive. Applicant's argue that the suture or string of Gabbay is not a "draw" string. Applicants state the string of Gabbay is not associated with "some structure" to cause bunching up to a folded state to thus constitute the string to be a "draw"string. However, Applicants fail to establish what structure Gabbay is lacking. It can be clearly seen (Fig. 4) that the sheet of tissue is bunched up and that the string as it is tightened and pulled results in a compact, bunched up configuration. Applicants state that there is nothing associated with the string of Gabbay and the associated length to result in the structure to be a drawstring associated with the tissue as claimed by Applicant. The Examiner is not convinced since the string of Gabbay clearly is "drawn" or pulled through points along the edge of the tissue and then results in pulled structure that the tissue is compacted or bunched together. Applicant fails to establish any structurally claimed difference from what Gabbay discloses.

Regarding the rejection of Muhanna in view of Lambrecht, the Applicants argue that the Muhanna tissue configuration is not a pleated structure. However, Muhanna clearly has a pleated configuration as interpreted to the definition presented above clearly has doubled over or folded the tissue material over such that it can be

considered pleaded. Applicants also present comments about the Lambrecht configuration relied on with the string through multiple sites that it passes through one side to another. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Thus, the Lambrecht teaching of using a drawstring to pass through multiple sites is the teaching the Examiner has taken from the reference to modify Muhanna to pass along the edge in the multiple locations to fold the tissue. Muhanna has already taught multiple site passes with strings but uses multiple strings, thus it would have been an obvious expedient to utilize one drawstring as taught by Lambrecht with Muhanna's structure and eliminate the use of multiple strings. Thus, the Examiner is of the position that since Muhanna has passed the strings through the tissue, it would be an obvious expedient to thus utilize one string as taught by Lambrecht. Additionally, both references illustrate folded configurations in the implanted state. Therefore the arguments are not persuasive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738